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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,338	10/23/2003	Terri L. Butler	BP. 028 US2	8488

7590 06/14/2007
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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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06/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/692,338

Applicant(s)

BUTLER ET AL.

Examiner

Traviss C. McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed 3/12/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1, 2, and 6 have been amended.

Claims 4-5 and 7-17 have been canceled.

Remarks drawn to rejections of Office Action mailed 2/26/2007 include:

Double patenting rejection: which has been maintained for reasons of record.

112 2nd paragraph rejection: which has been overcome by applicant's amendment and has been withdrawn.

An action on the merits of claims 1-3 and 6 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Double Patenting

The rejection of claims 1-3 and 6 as being provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-5 of copending Application No. 11/118,613 is being maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to treating vascular conditions using the same therapy. It is noted that the instant application is

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drawn to improving cardiovascular function in a subject with congestive heart failure and the '613 application is drawn to methods of improving ventilatory efficiency in a subject having reduced ventilatory efficiency, however, CHF is known to occur when the flow of blood from the heart decreases, or fluid backs up in the failing ventricle, or both, and thus increasing the blood flow from the heart would also be seen to improve ventilatory efficiency, as ventilatory efficiency is the rate at which CO₂ is removed from the body, thus dependent on the output rate of the heart. Thus, a subject having CHF, as in the instant application, is seen to be a subject that has reduced ventilatory efficiency as in the '613 patent. One of skill in the art would find it obvious that these applications are substantially overlapping in the subject matter that they are claiming.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that applicants stated they filed a terminal disclaimer to overcome this rejection, however, no terminal disclaimer was received.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 as amended requires the administration of ribose for a period of at least 3 weeks.

Applicants pointed to page 13, line 15 of their specification for support. However, page 13, line 15 involves the treatment of patients with chronic coronary artery disease (see page 13, lines 3-4), which is not a patient with peripheral vascular disease as required by claim 6. As such, there is not seen to be support for the claim as amended. The original disclosure does not provide any guidance for indicating that the compound must be administered for more than 3 weeks in treating peripheral vascular disease. The changing of the scope of a claim, either by broadening or narrowing, can be construed as new matter as either is capable of changing the scope of what is claimed, and the narrower or broader group must be supported in its entirety by the specification as originally filed.

It is noted that a rejection of the claims is reviewable by the Board of Patent Appeals and Interferences.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh
June 10, 2007

Shaojia A. Jiang
Supervisory Patent Examiner
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 6/11/07